

NIAD 213.1 (10103726)

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Fulbright &amp; Jaworski L.L.P.

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SEP 16 2003

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant : Jacobson, et al.  
Serial No. : 09/836,576  
Filed : April 16, 2001  
For : METHODS FOR IDENTIFYING REGULATORS OF  
PROTEIN-ADVANCED GLYCATION END PRODUCT  
(PROTEIN-AGE) FORMATION  
Art Unit : 1651  
Examiner : S. Saucier

September 16, 2003

Mail Stop: AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## AMENDMENT UNDER 37 C.F.R. § 1.116

SIR:

Responsive to the office action of July 31, 2003, please amend this application as follows:

IN THE CLAIMS

Please cancel claims 4, 5 and 12 without prejudice. Please amend the claims as follows:

Claim 1 (currently amended):

A method for determining if a substance ~~regulates glycation of a protein~~ is an inhibitor of protein glycation, comprising: (i) ~~administering histone H1 and ADP-ribose and determining~~

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~~glycation of histone H1 by ADP-ribose, (ii) admixing (i-a) a substance to be tested, wherein said substance is not aminoguanidine, (ii-b) histone H1, and (iii-c) ADP-ribose, and determining if said substance to be tested has an effect on glycation of histone H1 by ADP-ribose, wherein indication of an effect on said glycation by comparing the levels of glycation in the two assays, wherein a change in effect on glycation as compared to the first assay indicates that said substance regulates glycation~~

- (i) admixing ADP-ribose and histone H1 and determining fluorescence,
- (ii) admixing ADP-ribose, histone H1, and said substance, and determining fluorescence,
- (iii) comparing measured fluorescence in (i) and (ii), wherein a decrease in measured fluorescence in (ii) as compared to (i) is indicative of a possible protein glycation inhibitor,
- (iv) combining said possible protein glycation inhibitor with AGE-BSA, and measuring fluorescence,
- (v) measuring fluorescence of an amount of AGE-BSA equal to that in (iv),
- (vi) comparing fluorescence in (iv) and (v), wherein a decrease of fluorescence in (iv) as compared to (v) is indicative of a false positive, which quenches AGE fluorescence, and
- (viii) combining said substance if it does not quench AGE fluorescence with a protein, and determining damage done to said protein by said substance, wherein a lack of said damage indicates said substance is an inhibitor of protein glycation,

Claim 2 (original): The method of claim 1, wherein said substance is a dicarbonyl scavenger.

Claim 3 (original): The method of claim 1, wherein said substance is not an antioxidant.

Claim 4 (canceled)

Claim 5 (canceled)

Claim 6 (currently amended): The method of claim 1, comprising measuring fluorescence in steps (i) and (ii) about 5 days after admixing (a), (b), and (c).

1-68-12  
11 w/d  
1-68-10, 12  
referred

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Claim 7 (canceled)

Claim 8 (currently amended): The method of claim 1, further comprising determining damage done to said protein by said substance by determining cross-linking of molecules of histone H1.

Claim 9 (original): The method of claim 1, wherein said substance is a nucleophilic compound.

Claim 10 (previously presented): The method of claim 9, wherein said nucleophilic compound is a thiol containing compound.

Claim 11 (withdrawn): A kit useful in determining if a substance is capable of regulating protein glycation, comprising a container means, and separate portions of each of (i) histone H1 and (ii) ADP-ribose.

Claim 12 (canceled)